



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0536]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device User Fee Cover Sheet, Form FDA 3601 and Device Facility User Fee Cover Sheet, Form FDA 3601a

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review - Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0511. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Device User Fee Cover Sheet, Form FDA 3601 and Device Facility User Fee Cover
Sheet, Form FDA 3601a

OMB Control Number 0910-0511--Revision

The Federal Food, Drug, and Cosmetic Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107-250), and the Medical Device User Fee Amendments of 2007 (Title II of the Food and Drug Administration Amendments Act of 2007), authorizes FDA to collect user fees for certain medical device applications. Under this authority, companies pay a fee for certain new medical device applications or supplements submitted to the Agency for review. Because the submission of user fees concurrently with applications and supplements is required, the review of an application cannot begin until the fee is submitted. Form FDA 3601, the “Medical Device User Fee Cover Sheet,” is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference between the fees submitted for an application with the actual submitted application by using a unique number tracking system. The information collected is used by FDA’s Center for Devices and Radiological Health and FDA’s Center for Biologics Evaluation and Research to initiate the administrative screening of new medical device applications and supplemental applications.

We are revising the information collection to add Form FDA 3601a, the “Device Facility User Fee Cover Sheet.” Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States are required to register annually with FDA, a process known as establishment registration (21 CFR part 807, subparts A through D). (The information collection for medical device establishment registration and listing is approved under OMB control number 0910-0625.) All establishments required to register must pay a user fee. Form FDA 3601a, the

“Device Facility User Fee Cover Sheet,” is designed to collect payments for the annual establishment registration fee for medical device establishments.

The total number of annual responses for Form FDA 3601 is based on the average number of cover sheet submissions received by FDA in recent years. The number of received annual responses includes cover sheets for applications that were qualified for small businesses and fee waivers or reductions. The estimated hours per response are based on past FDA experience with the various cover sheet submissions and range from 5 to 30 minutes. For this analysis, we estimate 18 minutes per coversheet.

The total number of annual responses for Form FDA 3601a is based on the average number of cover sheet submissions received by FDA in recent years. Based on past FDA experience with various cover sheet submissions, we estimate 10 minutes per response.

In the *Federal Register* of June 12, 2020 (85 FR 35939), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although two comments were received, only one was responsive to the four collection of information topics solicited.

FDA’s response to the comment is that the establishment registration fee is not eligible for a reduced small business fee. This can be found on our website at:

<https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing>.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden^{1, 2}

FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
3601	6,182	1	6,182	0.30 (18 minutes)	1,855
3601a	24,086	1	24,086	0.17 (10 minutes)	4,095
Total			30,268		5,950

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Numbers have been rounded.

Our estimated burden for the information collection reflects an overall increase of 4,036 hours and a corresponding increase of 23,889 responses/records. We attribute these increases to

two factors: we have revised the burden estimate to include Form FDA 3601a and we have adjusted the number of respondents for Form FDA 3601 to reflect our current data.

Dated: August 31, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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